32. When the branded manufacturer's exclusivity ends and multiple generics enter the market, a branded drug often loses more than 80-90% of its market share within six months. Saunders Dep. 44:8-21; Tr. 802:5-8 (Kolassa), 376:12-17 (Berndt). Defendants' CEO saw this result of the statutory scheme as stacking the deck against Forest. Tr. 202:18-21 (Saunders) ("[T]he entire healthcare system is designed to benefit the generic companies and put up barriers and obstacles to the innovative companies, and so that's why you generally see the market shift 90/99 percent towards the generics."). This tradeoff of longer exclusivity rights for branded manufacturers like Forest, in return for quick and effective generic entry after loss of exclusivity, is the fundamental premise behind the policies and procedures that Congress enacted in the Hatch-Waxman Act, and which New York and other states embraced in their substitution laws. Berndt Decl. (PX64) ¶ 12-19; Tr. 339:19-340:18 (Berndt).

33. According to a 2013 study commissioned by the Generic Pharmaceutical Association, over the 10-year period from 2003 through 2012, generic drug use has generated more than $1.2 trillion in savings to the U.S. health care system by reduction in price over the branded drug. Generic Pharm. Ass'n, Generic

Drug Savings in the U.S. (PX8) at 1 (2013). In 2012, generic drugs saved the health system $217 billion. Id. Once patent exclusivity is lost, and generic entry occurs, the brand name manufacturer can expect a sharp drop in revenue, as it must choose between either competing by significantly lowering prices or accepting dramatically lower sales volume. This sharp drop in revenue has been referred to in this litigation and in the industry as the "patent cliff." Tr. 192:18-193:1 (Saunders), 386:2-11 (Berndt).

34. This AB-rated requirement, while intended to ensure therapeutic equivalence to the branded drug, provides an opportunity for branded manufacturers to game the system through a practice termed "product hopping." Tr. 453:19-454:12 (Berndt). For a drug that is about to go-off the "patent cliff," the drug manufacturer develops a "follow-on" version of the drug with a later patent expiration, and encourages patients and their physicians to switch to the new version. See Berndt Decl. (PX64) ¶ 41. As found above, the generic of the original version of the drug will not be "AB-rated" to the follow-on branded drug. Thus, if physicians write prescriptions for the follow-on version instead of the original, the generic entry is not dispensed even if, in practice, the cost savings offered by

the generic may outweigh any advantage offered by the new version of the branded drug.

35. Sometimes, these follow-on drugs may be better than the original version. Tr. 456:19-457:12 (Berndt). In other instances, the new drugs offer little to no therapeutic advantage over the prior formulation, and the reformulation is merely an attempt to manipulate the regulatory system and interfere with effective price competition between branded and generic drugs at the pharmacy. Tr. 453:19-454:12 (Berndt).

36. A branded manufacturer may use various tactics to encourage physicians and patients to switch to its new follow-on drug. Typically, the company will aggressively promote the follow-on drug and remove marketing effort behind the original drug, what has been termed a "soft switch." Berndt Decl. (PX64) ¶ 41; Tr. 221:5-9 (Saunders). A brand manufacturer that has successfully achieved a switch to a follow-on product can expect that most "switched" patients will not make a second switch back to the original product. Tr. 374:1-22 (Berndt).

III. The Development of the Namenda Franchise

A. The Success of Namenda IR

37. In June 2000, Forest obtained an exclusive license to U.S. Patent No. 5,061,703 held by Germany's Merz Pharma GmbH & Co. KGaA. In December 2002, Forest submitted an NDA to the FDA, seeking approval to market memantine HCL tablets (5mg and 10mg) branded as "Namenda" for the treatment of Alzheimer's. U.S. Food & Drug Admin., NDA 21-487 Approval Letter (DX782) (Oct. 16, 2003).

38. On October 16, 2003, the FDA approved Namenda Instant Release Tablets ("Namenda" or "Namenda IR") for the treatment of moderate-to-severe Alzheimer's disease. FDA Approval Letter, Application No. 21-487 from Robert Temple, Dir., Office of Drug Evaluation I, Ctr. for Drug Evaluation & Research, to Doreen V. Morgan, Forest Labs., Inc. (PX10) (Oct. 16, 2003). Forest brought Namenda IR to market in January of 2004. Press Release, Forest Labs., Inc., Namenda(TM) (memantine HCl), First Drug Approved For Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (PX11) (Jan. 13, 2004). Forest sought and received a five-year patent extension as compensation for the time spent obtaining FDA approval for Namenda tablets. 35 U.S.C. § 156; Tr. 340:15-340:18 (Berndt); Berndt Decl. (PX64) ¶ 92. As a result, Forest's main patent for

Namenda IR, the '703 patent, expires on April 11, 2015. U.S. Patent and Trademark Office, Patent Term Extensions (PX12).

39. At the time of the launch of Namenda IR tablets in January 2004, Namenda IR was the first and only medication approved for patients with moderate-to-severe Alzheimer's disease. See Tr. 124:21-125:09 (Stitt). Clinical trials established that Namenda IR is both safe and efficacious as a monotherapy. Reisberg Dep. 156:19-157:19, 196:12-199:20 (discussing the studies); Press Release, Forest Labs., Namenda(TM) (memantine HCl), First Drug Approved for Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (DX484) (Jan. 13, 2004). Leading Alzheimer's experts confirm the salutary effect Namenda has made in the everyday lives of Alzheimer's patients. See Reisberg Decl. (PX352) ¶ 24; Rovner Decl. (PX358) ¶ 39. Alzheimer's patients taking Namenda more easily perform "common activities of daily living such as eating, walking, toileting, bathing, and dressing." Press Release, Forest Labs., Namenda(TM) (memantine HCl), First Drug Approved for Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (DX484) (Jan. 13, 2004). Namenda IR is administered twice a day. Lah Dep. 191:4-6.

40. In 2005, Forest introduced a liquid form of Namenda IR (often referred to as an "oral solution") for patients who have difficulty swallowing tablets, although any Namenda patient can take it. Meury Decl. (DX720) ¶ 7; Lah Decl. (PX85) ¶ 13; Lah Dep. (DX487) 192:10-13; see also Jacobs Dep. 104:23-105:9 (CD Ex. 41); Rovner Dep. 210:2-13 (CD Ex. 28); Reisberg Dep. 117:5-118:6; Solomon Decl. (DX718) ¶ 6. Namenda IR oral solution is an immediate-release product that has the same active ingredient as Namenda IR tablets and is as effective as the tablets. See Lah Dep. (DX487) 186:16-25, 191:4-23, 284:8:14. The oral solution originally was covered by the same FDA-approved label as the tablets. Namenda Package Insert (DX456) (Oct. 2013); Lah Dep. (DX487) 284:15-22. As of August 2014, the tablets and the oral solution are covered under separate labels. See Namenda Oral Solution Package Insert (Aug. 2014) (CD Ex. 47). Like Namenda IR tablets, the oral solution should be administered twice a day. Lah Dep. (DX487) 191:4-6; Jacobs Decl. (CD Ex. 11) ¶ 25; Ferris Decl. (CD Ex. 20) ¶ 15; Kohrman Decl. (CD Ex. 15) ¶ 21; Reisberg Decl. (CD Ex. 13) ¶ 25; Rovner Decl. (CD Ex. 18) ¶ 31; Meury Decl. (DX720) ¶ 9; Solomon Decl. (CD Ex. 16) ¶ 7.

41. In 2009 and 2010, Forest, as a resolution of patent litigation, entered into licensing agreements with ten generic competitors allowing for the sale of generic memantine ("generic Namenda" or "generic IR") tablets on July 11, 2015, three months before Forest's exclusivity ends, or earlier in certain circumstances. See also Solomon Decl. (DX718) ¶¶ 13-14; Press Release, Forest Labs., Forest and Merz Pharma GmbH & Co. KGaA Settle Namenda IR Patent Litigation (DX781) (July 22, 2010). Five generic manufacturers have obtained and currently maintain tentative approval from the FDA to market their generic versions of Namenda IR tablets as early as July 11, 2015. Solomon Decl. (DX718) ¶ 14. Seven more generic competitors may begin selling their generic versions of generic Namenda IR tablets as early as October 11, 2015. Solomon Decl. (DX718) ¶ 16.

42. In 2009, Forest began a large program to evaluate whether memantine could be approved to treat pediatric autism at the FDA's "official request," known as a "Pediatric Written Request" ("PWR"). Taglietti Decl. ¶¶ 25-26; Taglietti Dep. (CD Ex. 42) 235:8-236:19; Solomon Dep. (CD Ex. 39) 227:20-237:8 (explaining full background of autism studies). On June 18, 2014, Forest announced that FDA had granted its request for

pediatric exclusivity, extending Forest's exclusivity rights for another six months. Press Release, Forest Labs., Inc., Forest Obtains Six Months U.S. Pediatric Exclusivity for Namenda R and Namenda XR (PX13) (June 18, 2014). This extended the patent exclusivity to October 11, 2015. Solomon Decl. (DX16) ¶ 15.

43. Forest invested almost $70 million in support of clinical studies for the treatment of pediatric autism. Taglietti Decl. (DX303) ¶ 25; Saunders Dep. (CD Ex. 38) 318:13-17. At that time, it was the "largest study ever done on autistic patients." Taglietti Dep. (CD Ex. 42) 237:3-7. In designing and running these clinical studies for pediatric autism, Forest "developed for the first time a network of over 185 clinical study sites for autism that had never existed before." Taglietti Decl. (DX303) ¶ 28.

44. Sales of Namenda IR for 2013 have exceeded $1.5 billion and 2012 had similar results. Kolassa Decl. (DX821) ¶ 5; Nikhil Nayak email re: FW: Namenda Manager's Meeting Draft Script (PX70) at FRX-NY-01634297.

B. Introduction of Namenda XR And Its Place In The Franchise

45. Between 2006 and 2014, Forest invested approximately [redacted] in R&D for an improved version of Namenda: a once-daily extended release capsule called Namenda XR. Meury Decl. (DX720) ¶¶ 5, 8. All currently marketed symptomatic treatments for Alzheimer's disease had already moved to once-a-day treatments before the introduction of Namenda XR. Ferris Dep. 107:16-109:9; Reisberg Dep. 165:23-166:8.

46. As Dr. Reisberg testified:

> [T]here is an exponential difference between being able to take a medicine once daily versus twice daily. And I think all of us have taken medications know this, that it's much easier to take a medicine once a day than twice a day. But these differences become very much compounded for my patients. So persons with Alzheimer's disease are frequently older, and older people take more medications than younger people. And persons with memory problems have difficulty taking medication.

Reisberg Hr'g 727:6-728:8; Reisberg Dep. 136:5-137:8. All Defendants' medical experts echoed Dr. Reisberg's statements. Kohrman Hr'g 740:1-9; Rovner Dep. 271:16-25; Ferris Dep. 317:17-318:11; Jacobs Dep. 217:20-219:15. Fewer pills generally lead to greater compliance with treatment. Lah Hr'g 95:5-7; Lah Dep. 137:13-138:24; Kohrman Decl. (PX315) ¶¶ 3, 24-28 (once-daily dosing increases compliance); Reisberg Decl. (PX352) ¶¶ 30-31;

Rovner Decl. (PX358) ¶ 37; Ferris Dep. 112:8-10; Jacobs Dep. 218:24-220:16.

47. "Many controlled clinical trials have also shown that 'extended-release agents are associated with improved tolerability, greater patient adherence to treatment, reduced total treatment costs, and better long-term clinical outcomes.'" Cremieux (PX229) ¶ 18. Some Alzheimer's disease patients experience "sundowning," which is the "tendency for some patients with Alzheimer's disease to become more confused, anxious, paranoid, [and] restless later in the day than earlier in the day." Rovner Dep. 245:8-14; Kohrman Hr'g 740:3-9; Polivka-West Dep. 120:10-121:6. As Dr. Lah testified, "sundowning may lead to agitation" which "may make it more difficult to get the patient the medication they need." Lah Hr'g 98:18-99:2; Lah Dep. 173:16-18; see also Rovner Dep. 247:21-248:2 (reporting that half of his sundowning patients have trouble taking medication at night); Rovner Decl. (PX358) ¶¶ 41-42; Ferris Decl. (PX276) ¶ 41; Hausman Hr'g 714:13-15 (acknowledging caregiver burden and difficulties associated with getting patients to take a drug in the afternoon).

48. Forest is the sole owner (through its subsidiary) or exclusive licensee of all patents covering Namenda XR listed in the Orange Book. See Food & Drug Admin., Orange Book: Approved Drug Products with Therapeutic Equivalence Functions (DX388) (2014). The FDA approved once-daily Namenda XR in June 2010. Meury IH Tr. (DX488) 160:22-24; Taglietti Dep. 166:20-22 (CD Ex. 42). The patents that cover Namenda XR expire in 2029, several years after those covering the original Namenda IR. Tr. 598:21-599:1 (Meury); U.S. Food & Drug Admin., Orange Book: Approve Drug Products with Therapeutic Equivalence Evaluations (PX18). Forest is in litigation with potential generic competitors over these patents [redacted] Tr. 203:8-23 (Saunders).

49. In the summer of 2011, Forest worked with market research firm GfK Healthcare to learn more about caregiver burdens and preferences and obtain caregiver feedback regarding Namenda and a potential Namenda XR combination therapy. GfK Healthcare, 2011 Alzheimer's Disease Caregiver Study (CD Ex. 4) (Aug. 15, 2011). In late 2012, GfK surveyed physicians on behalf of Forest, in part, to gauge awareness of the upcoming Namenda XR. GfK Healthcare, 2012 Alzheimer's Disease Physician

Study (CD Ex. 3) (Dec. 20, 2012). Forest conducted further research in the spring of 2013. GfK Healthcare, Namenda Caregiver Research, Final Presentation (DX496) (May 2013).

50. In the 2013 survey, caregivers reported that they viewed Namenda XR as a "meaningful and welcome improvement" over the twice-a-day Namenda IR tablets. Id. at 6, 33 (emphasis added). Eighty percent of caregivers interviewed responded that they were likely to ask the patients' physicians about Namenda XR. Id. at 33.

51. Defendants obtained survey results that 90% of physicians support the switch from Namenda IR to Namenda XR. Tr. 34:18-22 (showing slide and citing 93% approval for discontinuation plan in opening statement). However, the 90% figure is based on a single question that sought a rating from 1 to 10, but first instructed the physicians to assume caregiver and patient satisfaction. Tr. 505:7-506:17. Other open-ended questions indicate that some doctors were outraged by the forced switch scheme. Tr. 513:17-18.

52. Forest did not bring Namenda XR to market until July 21, 2013. FDA Approval Letter, Application No. 22-525 from Russell Katz Dir., Div. of Neurology Prods., Office of Drug

Evaluation I, Ctr. for Drug Evaluation & Research, to Michael P. Niebo, Forest Labs., Inc. (PX20) (June 21, 2010); Press Release, Forest Labs., Inc., Forest Announces U.S. Availability of New Once-Daily NAMENDA XR (PX21) (June 13, 2013). At that time, generic competition for Namenda IR was imminent, and Namenda XR was needed to accomplish the product extension strategy to protect its share of the market.

53. Forest spent approximately [redacted] educating patients, caregivers, health care providers, and pharmacists about Namenda XR, including Namenda XR's benefits and FDA-approved instructions for transitioning from Namenda IR to Namenda XR. Namenda XR Package Insert § 2.2 (Sept. 2014) (DX368); Meury Decl. ¶ 10 (DX720); Hausman Decl. ¶ 22 (PX287). After launching Namenda XR, Forest sold Namenda IR tablets, IR oral solution, and Namenda XR capsules concurrently. Taglietti Decl. ¶ 29 (DX303).

54. Namenda XR has the same therapeutic effect as Namenda IR but because of its one-a-day dosage it can reduce costs based on the number of pills administered by a caregiver, the time expended in pill administration. Tr. 59:12-13 (Lah).

55. Defendants are in the process of developing and/or marketing another future product, a Fixed Dose Combination ("FDC"), that combines Namenda XR with donepezil, the once-a-day CI, in one pill. Meury Decl. (DX720) ¶ 9; see Taglietti Decl. (DX303) ¶¶ 17-20; Meury Dep. 26:24-27:2. Defendants are currently seeking FDA approval for the FDC product. Saunders Hr'g 272:23-273:3.

IV. Defendants Have Monopoly Power

A. Medical Practice Demonstrates Memantine Is Its Own Market

56. In practice, doctors commonly prescribe a CI in the early stage of the disease. Tr. 54:12-18 (Lah); Tr. 732:21-733:4 (Reisberg). Namenda is prescribed in the moderate-to-severe stages, in addition to the CI, or alone if CIs cannot be tolerated due to side effects. Lah Decl. (PX85) ¶ 9; Tr. 54:19-55:1 (Lah); Tr. 732:21-733:4 (Reisberg); Tr. 760:1-6, 760:16-24 (Kohrman); Jacobs Dep. 92:14-93:10; 102:6-19 (explaining that all patients who clinically qualify to take a CI are prescribed one unless they have side effects, and explaining the differences between the functions of memantine and CIs); Jacobs

Dep. 102:6-19 ("[T]he cholinesterase inhibitor will be most effective when there is cholinergic deficiency at the same time that there is neurons around to utilize the return of acetylcholine and . . . memantine will be more effective any time the brain cells are leaking calcium"); Rovner Dep. 68:25-69:11 ("Q. They complement one another, would you say? A. They work in different ways, and tackle the problem from different directions, but they all have the same focus. Q. So they work with differing mechanisms? A. That's right."); see also "Namenda Franchise Business Plan" (PX68) at FRX-NY-01648216 ("As Aricept is indicated for mild patients it is usually initiated first. Namenda is usually added when the patient progresses to the moderate stage of the disease . . . .").

57. Namenda IR is not indicated for use with mild-stage Alzheimer's Disease patients. FDA "Highlights of Prescribing Information (PX109) (Sept. 2014). Using Namenda for early Alzheimer's patients has little clinical support. Press Release, Forest Labs., Inc., Forest Laboratories Announces FDA Decision on Supplemental New Drug Application for Namenda® (PX43) (Jul. 25, 2005).

58. Doctors do not consider CIs to be reasonable substitutes for Namenda. Tr. 63:18-64:1 (Lah); Lah Decl. (PX85) ¶ 7 ("To the best of my knowledge, there are not therapeutic substitutes for Namenda currently on the market"), ¶ 10 ("Almost all of my patients who take Namenda also take a CI. The two drugs are not interchangeable; rather, they seem to have the greatest beneficial effect when they are used together"); Tr. 760:15-24 (Kohrman) ("[I]n the mild stage of the disease the typical way of approaching this is that . . . I will prescribe a cholinesterase inhibitor, calling it a CI . . . and if they progress into the moderate or moderate to severe stage, at that point continuing the cholinesterase inhibitor, I will add Namenda to that regimen"); Jacobs Dep. 106:7-23 ("I . . . start with a cholinesterase inhibitor, because I am usually seeing them earlier in the phase of their dementia syndrome, and then try to get them on both drugs because that's two different types of good band-aids to help them think better.").

59. Doctors do not switch patients from Namenda to a more affordable CI because they are not substitutes for one another. Tr. 63:18-64:1 (Lah) ("Q. Did you consider switching your patients on Namenda IR to a cholinesterase inhibitor? A. No. Q. Why not? A. That wouldn't make any sense. Q. Why not?

A. The drugs very different. So Namenda works by an entirely different mechanism than any of the cholinesterase inhibitors, so they're not equivalent drugs.")

60. Instead, the two classes of drugs are complements: 70% of Namenda patients also take an ACI. Tr. 609:9-19 (Meury); Namenda Franchise Business Plan (PX24) at FRX-NY-01686842; Forest Laboratories Management Discusses Q2 2014 Results, Earnings Call Transcript at 4 (PX485); Jennifer Rinaldo email re: Namenda and Carip Business Reviews (PX68) at FRX-NY-01648216; Tr. 883:11-14 (Cremieux).

61. Even in instances where memantine is prescribed without a CI, i.e., as a monotherapy, it is the severity of the CIs' side-effects that eliminates that class of drugs altogether as a viable therapy. Lah Decl. (PX85) ¶ 9; Tr. 54:19-55:1 (Lah); Tr. 732:21-733:4 (Reisberg); Tr. 760:1-6, 760:16-24 (Kohrman); Jacobs Dep. 92:14-93:10, 102:6-19.

62. Thus, whether prescribed alongside CIs or as a monotherapy, medical practice establishes that memantine is not a substitute for CIs.

B. Empirical Analysis Demonstrates Memantine Is Its Own Market

63. The economic evidence also establishes that CIs are not reasonable substitutes for Namenda. Tr. 346:16-348:8; 351:17-20: 352:3-5; Tr. 358:16-20 (Berndt); Berndt Decl. (PX64) ¶¶ 23-28; Tr. 359:15-361:2 (Berndt) (discussing PX331).

64. Dr. Berndt's study of the cross elasticity of demand between Namenda IR and a generic form of one of the CIs, donepezil, demonstrated little to no switching from Namenda to donepezil when the relative price of donepezil fell. Tr. 351:3-20 (Berndt); Tr. 346:16-351:15; 351:25-6; 352:7-22 (Berndt); Berndt Decl. ¶¶ 29-32. This pattern continued for a number of years after the relative drop in donepezil's price, in fact memantine's demand slightly increased following the donepezil relative price reduction, suggesting the two medications are complements rather than substitutes. Tr. 355:14-356:4 (Berndt). This finding establishes a low cross elasticity of demand between the two drugs, and supports the State's contention that memantine and CIs do not comprise one market of competing Alzheimer's drugs.

65. Dr. Cremieux's, Defendants' expert's, conclusion that cross elasticity of demand between memantine and donepezil

was substantial is not as persuasive as Dr. Berndt's. Dr. Cremieux's conclusions were based on a data sample of approximately less than 600 prescriptions from one employer. Tr. 362:11-363:11 (Berndt). By contrast, Dr. Berndt's conclusion was based upon the behavior of multiple payors, representing over one million prescriptions pulled from the entire U.S. market. Tr. 362:11-363:11 (Berndt). Moreover, Dr. Cremieux's dataset reflected changes to patients' copayments alone, while Dr. Berndt's data included both health plan and patient costs. Tr. 367:10-9 (Berndt).

66. Dr. Cremieux's other principal analysis is based upon a 2013 Forest study documenting "reversals," i.e., where a Namenda XR patient does not fill his prescription, and "rejections," i.e., where a Namenda XR patient's insurance company refuses to pay for Namenda XR. See DX093; Cremieux Dep. 165:15-168. Patient reversals are not useful proxies for substitutability. Substitutability assumes that changes in relative price result in changes in demand. Reversals in this data set, on the other hand, do not control for other non-price factors that may affect a patient's decision to refuse XR, such as an increase in negative side-effects when switching from CIs to memantine. Payor rejections are likewise ill-suited to a substitutability analysis. Defendants study shows that [redacted] of

those Namenda XR prescriptions that were rejected by payors were filled with another product. DX093 at slides 2, 6. Of this [redacted] group, about [redacted] were filled with Namenda IR, and roughly the remaining [redacted] were filled with a CI. [redacted] But an insurer refusal to pay for the Namenda XR is equivalent to a highly significant price increase on that drug since the patient sees his effective price shift from the co-payment to the full retail price of the drug. Therefore, the ratio of the two, the cross-elasticity, is too small to demonstrate substitutability.

67. To the extent that Dr. Berndt's and Dr. Cremieux's cross elasticity of demand analyses conflict, Dr. Berndt's relatively data-rich analysis is more credible.

C. Defendants' Business Strategy Demonstrates Memantine Is Its Own Market

68. In addition to medical practice and empirical evidence, Defendants' own withdrawal strategy illustrates that CIs are not substitutes for NMDA receptor antagonists such as Namenda IR. If they were, Forest's withdrawal of Namenda IR

from the market would drive Namenda patients to CIs, many of which are much less expensive than Namenda XR. Indeed, it is the complementary nature of CIs and memantine that gives Defendants' FDC product a comparative advantage. Meury Hr'g 566:4-23; see also Hausman Hr'g 664:11-665:6. Meury Decl. ¶ 9 (DX720); see Taglietti ¶¶ 17-20 (DX303); Meury Dep. 26:24-27:2. Defendants are experienced producers in the market that have premised their Namenda IR strategy on the absence of substitutes for memantine. Defendants' studies predict that approximately [redacted] or more of Namenda IR patients will switch to Namenda XR as a result of the intended discontinuation. Presentation titled "Namenda IR & XR Conversion Plan" (PX31). In January 2013, a Forest employee expressed confidence that discontinuing Namenda would likely be successful because, unlike other attempts to pursue similar product extension strategies, "there are no alternatives" to Namenda—"although of course patients could simply stop taking the drug." Presentation titled "Namenda IR & XR Conversion Plan" (PX31) at FRX-NY-01575875. This was so, even though donepezil (the generic version of Aricept) has been and continues to be priced significantly lower than Namenda XR. Tr. 892:8-25 (Cremieux).

69. Accordingly, NMDA receptor antagonists, including Namenda IR, Namenda XR, and any future AB-rated generics that may enter constitute the relevant product market ("memantine market"). Tr. 336:14-16 (Berndt). Defendants currently have all of the sales in that market. Tr. 344:9-19 (Berndt). Patents and other regulatory requirements presently prevent potential competitors from entering that market.

70. There is no dispute that the relevant geographic market is the United States.

V. Forest's Anti-Competitive Conduct

A. Defendants Strategies to Avoid the Patent Cliff

71. If Defendants maintain the status quo with respect to IR sales and distribution, generic memantine will have about 80% of the total memantine market within three months and 90% after twelve. Berndt Decl. (PX064) ¶ 63.

72. By Fall 2012, Forest was considering ways to convert patients from IR to XR prior to the availability of generic memantine. PX14-PX17. Forest emphasized the importance

of switching patients from Namenda IR to Namenda XR in internal documents, sales training, and public statements. In June of 2013, for example, an executive made a speech at a Namenda XR launch event:

> Our mission is to convert to Namenda XR and lift the franchise as a result of increased sales calls and combination therapy usage . . . . Make no mistake about it, this is a sprint. We need to convert as much IR business to Namenda XR as quickly as possible.

PX22 (Speech from Namenda XR launch event, June 2013) at FRX-NY-01573603-04. Another executive wrote in a draft speech:

> [T]he core of our brand strategy with XR is to convert our existing IR business to Namenda XR as fast as we can and also gain new starts for Namenda XR. We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.

PX23 at FRX-NY-01574212.

73. In June 2013, Forest's senior marketing executives considered two alternatives to the typical soft switch approach described above: completely discontinuing Namenda IR; or "technically" leaving the drug on the market, but severely restricting patient access with "limited distribution." Presentation titled "Namenda IR & XR Conversion Plan" (PX31).

74. In a presentation contained in a June 26, 2013 email between two of Defendants' executives dated, the author notes that, with respect to Forest's conversion strategy, "[e]ither [a withdrawal or limited distribution] approach is unprecedented . . . [we] would be operating in uncharted territory." Namenda IR + XR Conversion Project (PX32) at slide 4. The presentation also notes that "Prescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment." Namenda IR + XR Conversion Project (PX32) at slide 4; see also PX14; Tr. 183:22-184:17 (Stitt) (describing differences between the Namenda IR hard switch and prior situations where there were substitutes for the discontinued drug: "So the unique thing here I think is that there's really no place for prescribers to, to go with a drug to treat that condition.").

75. On October 18, 2013, a Forest executive emailed his colleagues, announcing the decision to withdraw Namenda from the market: "Dear all: Forest has made the decision to discontinue sales of Namenda IR and transition all patients to Namenda XR." Saunders testified that he made the decision. Tr.

262:18-23 (Saunders). By doing the hard switch, Forest hoped to hold on to a large share of its base instead of losing them to competition. Tr. 219:12-16 (Saunders).

76. In a January earnings call, Saunders explained that the purpose of the hard switch was to protect the company's Namenda revenues from declining too quickly after generic entry and the ensuing "patent cliff":

> [I]f we do the hard switch and we convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs. They don't have the sales force. They don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult and is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff.

Tr. Of Jan. 21, 2014 earnings call, annexed to Zain Decl. as Ex. 1.

77. On February 14, 2014, Forest began the "forced switch" by publicly announcing that Namenda IR tablets would be discontinued on August 15, 2014. Press Release, Forest Labs., Inc., Forest Laboratories to Discontinue Namenda Tablets, Focus on Once-Daily Namenda XR (Feb. 14, 2014), annexed to Zain Decl. as Ex. 33. That same day, Forest notified the FDA that it would

"be discontinuing the sale of Namenda Tablets effective August 15, 2014." Zain Decl. Ex. 34. Forest also published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR and urging caregivers to speak with their loved ones' "healthcare provider[s] as soon as possible to discuss switching to Namenda XR." Patrick Boen letter to healthcare providers (PX37).

78. Forest's announcements of its plans for discontinuance were made to alert physicians and patients that Forest would be discontinuing IR so they could take appropriate actions. Tr. 616: 18-20 (Meury). Physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR. Tr. 61:8-19 (Lah) (viewing the announcement as forcing a "wholesale switch" of patients from Namenda IR to Namenda XR).

79. In its Form 10-K filing with the Securities and Exchange Commission for fiscal year 2013 (ending March 31, 2014), Forest made representations that it would discontinue Namenda IR on August 15, 2014. In Item 7, which relates to "Management's Discussion and Analysis of Financial Condition and Results of Operations," Forest's 10-K reads: "In February 2014,

the Company announced that it would discontinue the sale of Namenda tablets effective August 15, 2014."

80. Forest sought to convert the drug's largest customer base, Medicare patients, from XR to IR by having the CMS remove IR from its FRF. On Feb. 5, 2014, a Forest employee wrote an email to the Defendants' Executive Vice President for Sales stating:

> I propose that we have a letter to CMS and also place a call to the agency. We need to ask CMS to REMOVE [Namenda] IR from the Formulary Reference File. That way, the plans won't see it when they create their own formularies.

Decl. Ex. 39 at FRX-NY-01596407. The letter was approved and sent. Amanda Seef-Charny email re: FW: Forest Laboratories to Discontinue Namenda® Tablets, Focus Once-Daily Namenda XR® (PX39). Defendants' expert pharmaceutical consultant witness testified that she has never in her consulting experience heard of a company sending such a letter. Edgar Hr'g 63:24-25. If the drug is not on the FRF, health plans are less likely to include it in their formularies and, thus, health plans may not cover Namenda tablets starting in January 2015. Stitt Decl. (PX122) ¶¶ 29-31.

81. As Forest sought to accomplish the switch from IR to XR, Forest executives began to express concerns that their efforts would be insufficient to switch a high enough number of patients from Namenda IR to Namenda XR prior to the market entry of generic memantine. William Meury email re: Namenda XR Weekly Performance Tracker - WE 8-9-13 (PX28) at FRX-NY-01618169-70.

82. Patients and their physicians are reluctant to switch from Namenda IR to Namenda XR. Lah Decl. (PX85) ¶¶ 11, 22, 25. The benefits of a switch from Namenda IR to Namenda XR are often marginal. Tr. 58:5-15 (Lah); Lah Decl. (PX85) ¶ 15 ("In my experience, compliance has not been a problem. A twice-daily regimen is easy to follow . . . ."). No studies have been done to show that Namenda XR is more effective than Namenda IR. Taglietti Dep. 181:7-16, 211:22-212:7. Being able to take Namenda once a day instead of twice, is not a significant benefit for patients already taking other twice-daily medications. Lah Decl. (PX85) ¶¶ 15, 22.

83. According to Polivka-West, most Alzheimer's patients are in a long-term care facility (Tr. 626:6-13)

(Polivka-West), and that the average patient in a long-term care facility takes nine pills per day. Tr. 641:5-22 (Polivka-West). She also testified that long-term care facilities generally dispense pills three times a day. Tr. 640:4-6 (Polivka-West). Thus, a patient that switches from Namenda IR to Namenda XR might go from nine pills a day to eight pills a day, Tr. 642:5-8 (Polivka-West), and given that pills are dispensed three times a day, it is possible that the patient is still going to have to take pills multiple times per day. Tr. 642:9-12 (Polivka-West).

84. Only half of all patients are willing to pay more money out-of-pocket to reduce their pill burden by half (e.g. going from eight pills per day to four). Tr. 642:13-643:17 (Polivka-West) & Pill Burden in Hypertensive Patients Treated with Single-Pill Combination Therapy: An Observational Study (PX349) at 414.

85. For some patients (and their physicians), the benefits of the change to Namenda XR are outweighed by the risks of changing the medical routine of a highly vulnerable patient. As Dr. Lah explained:

> For Alzheimer's patients, stability is key: this is a very vulnerable group of patients. Any small change

> in medication raises the risk of an adverse effect. As Namenda is typically prescribed in the mid to later phases of Alzheimer's disease, the patients taking Namenda are at a stage in the disease when they are especially vulnerable. Even a small change in a patient's condition can require him or her to be moved to a care facility.

PX85 (Lah Decl.) ¶ 24; PX64 (Berndt Decl.) ¶ 84 (discussing reasons why twice-daily Namenda may be preferred by some patients).

86. Given the potential risks, without studies that show that a new medication has meaningful benefits over a patient's current medication, physicians frequently will not switch an Alzheimer's patient from a medicine on which the patient is doing well. Tr. 58:5-15 (Lah); Lah Decl. (PX85) ¶ 25; Rovner Dep. 106:18-25, Oct. 29, 2014 ("Q. And if the caregiver said I would rather just keep my husband or wife on the medication they're taking, they seem to be doing fine, what would you do? A. I would go along with that.").

87. As a result, despite aggressive marketing and pricing practices typical of a soft switch, Forest forecasted in late 2013 that only about [redacted] of patients using Namenda IR tablets could be voluntarily converted to Namenda XR prior to availability of generic Namenda IR. William Meury email re:

Namenda Financials (PX29) at FRX-NY-01566763. If physicians and patients had the choice, many would stay on the original formulation. As one Forest executive stated, "I could see doctors just being apathetic about it and if patient is fine and not complaining of any issues, why switch?" William Meury email re: Namenda XR Weekly Performance Tracker - WE 8-9-13 (PX28) at FRX-NY-01618168.

88. For Forest's plan to avoid the "patent cliff" to be successful Forest had to switch large numbers of patients from Namenda IR to Namenda XR. Tr. 412:15-20 (Berndt); Berndt Decl. (PX64) ¶¶ 76, 79. Forest also realized that, to be successful, its product switch had to be accomplished before less expensive generic versions of Namenda IR tablets became available in the market. Transcript of Forest Earnings Call, January 17, 2014 (PX3) at FRX-NY-01642564 (Saunders: "IR will go generic in July of 2015. And so the sweet spot for a [Namenda] switch would be in the fall [of 2014]"). Once generic memantine became available, generic and branded Namenda IR would be AB substitutable at the pharmacy, and most patients with prescriptions for Namenda IR would likely switch to generic memantine instead of Namenda XR. Tr. 375:21-376:5 (Berndt).

89. If, however, Forest could get patients, physicians, and insurers to switch to Namenda XR before the entry of generic memantine, Forest would be able to prevent manufacturers of generic Namenda IR from effectively competing for those patients. Generic memantine tablets would not be AB-substitutable for Namenda XR under state substitution laws. A pharmacist would have to call the prescribing physician in order to substitute lower-priced generic memantine for branded Namenda XR. Stitt Decl. (PX122) ¶ 38; Tr. 409:9-23 (Berndt).

90. Forest gave priority to converting patients from Namenda IR to Namenda XR as quickly as possible. In Defendants' CEO's words, "I think our view is that what we're trying to do is make a cliff disappear." Tr. 197:5-22. It was one of the three key elements in its strategy to protect the Namenda franchise sales stream. Tr. 201:9-18 (Saunders); Transcript of Forest Earnings Call, January 17, 2014 (PX3) at 8; Namenda Transition PowerPoint presentation, Dec. 2013 (PX363).

91. Forest's CEO stated during a January analyst call: "We're very focused on our Namenda conversion . . . if you kind of look at the timing of IR, IR will go generic in July of 2015. And so the sweet spot for a switch would be in the fall,

and so that's kind of how we're thinking about it." Transcript of Forest Earnings Call, January 17, 2014 (PX3) at 2. A document titled "Namenda Franchise Business Plan" dated September 2013 specifically explains that the sales target for "converting" Namenda patients must be achieved "prior to the Namenda LOE [loss of exclusivity] in 2015." FRX-NY-01686842 (PX24).

92. A separate presentation lists "Maximize XR Conversion leading up to IR LOE [loss of exclusivity]" as a key part of Forest's strategy for convincing health plans to pay for Namenda XR. Namenda XR FY15 Business Plan Managed Care (PX25) at 4. Forest agreed to pay [redacted] rebates to health plans to make sure they put Namenda XR on the same tier as Namenda IR so that members would not have an incentive to choose Namenda IR. Carolyn Myers email re: FW: Namenda (PX15).

93. The total promotional budget for the Namenda franchise in fiscal year 2014 [redacted], with "[a]ll funds . . . allocated to drive conversion from Namenda to Namenda XR." Namenda Franchise Plan (PX24) at FRX-NY-01686845. Last year, Forest spent hundreds of millions of dollars detailing, i.e., visiting doctors to promote, Namenda XR. Tr.

231:14-17 (Saunders). Forest knew that once generic Namenda IR entered the market, it would be even more difficult and expensive to promote Namenda XR. Tr. 218:21-23 (Saunders).

94. Since 2013, Forest has undertaken an aggressive marketing campaign aimed at converting as many IR patients to XR as quickly as possible prior to Namenda IR losing exclusivity. [redacted]

95. As found above, third party payors use formularies to influence the drugs doctors prescribe and patients take. To achieve formulary coverage for Namenda XR, Forest negotiated with health plans to obtain "preferred brand" status with top Part D plans nationally. See Hausman Decl. (PX287) ¶ 13, tbl. 1; Meury Dep. 22:3-25; Kane Dep. 276:25-277:4; Meury Decl. (DX720) ¶ 12; Devlin Dep. 118:25-119:5 (Forest negotiated to get XR on formularies after launch). The lower co-pay associated with "preferred brand" status lowers the

price to patients and can be crucial to a new drug's success because better formulary positioning results in substantially higher demand. See Hausman ¶ 12 (PX287); Hausman Hr'g 659:23-662:3 (testifying that formulary tier status can result in $350 to $1000 a year savings to a patient and provide "an incentive to switch"). For patients, because "nonpreferred" brands have higher co-pays, the negotiated "preferred brand" formulary position can result in patient savings of up to $40 per prescription, depending on the plan. Tr. 111:23-112:5 (Stitt). For other plans with three rather than four tiers, Forest achieved a tier status identical to Namenda IR in most cases. Devlin Dep. 127:19-148:10; PX242-PX251 (formularies for several health plans).

96. Forest discounted Namenda XR at a minimum of 5% discount from the wholesale acquisition cost ("WAC") of the Namenda IR tablets. Meury Decl. (DX720) ¶ 12; Kane Dep. 275:23-276:10. On average, the discount of XR is [redacted] off the average selling price of Namenda IR. See Meury Dep. 23:3-7. Where additional discounts apply, Forest positioned Namenda XR to be over [redacted] less expensive for health plans than Namenda IR tablets. Meury Decl. (DX720) ¶ 12.

97. Discounts that Forest offered ranged "anywhere from [redacted] percent." Devlin Dep. 120:10-18; Meury Hr'g 593:24-594:1 ("We have to negotiate . . . in some cases [redacted] discounts with health plans . . . ."). For example, one of the [redacted] providers "of the Medicare Part D benefit in the country" secured a discount of over [redacted]. Meury Hr'g 579:9-14. In 2014, managed care organizations paid approximately [redacted] less for Namenda XR than for Namenda IR. Meury Dep. 22:21-25. Meury testified that when the "tidal wave" of generics comes in 2015, [redacted] Meury Hr'g 594:6-9. The total discounts given by Forest exceed [redacted]. See Meury Hr'g 580:20-581:5.

98. During the same period, executives at Forest became aware that problems in the manufacturing and supply of Namenda XR presented a substantial risk that they would be unable to discontinue Namenda IR and effectively implement the proposed forced switch by August 15, 2014 because it would be unable to supply the market with sufficient Namenda XR. Stewart Decl. (DX717) ¶ 10; Meury Decl. (DX720) ¶¶ 22-23; Press Release, Forest Labs., Forest Laboratories Announces Intention to